POLICY

Assessment of financial conflict of interest is required for all clinical research protocols that may lead to the financial benefit or loss of any individual or entity.

PURPOSE

To identify the process for submitting the Personal Financial Holdings (PFH) form via iRIS to the NCI Deputy Ethics Counselor (DEC) for review.

RESOURCES


PROCEDURES

STEP 1: PREPARATION PRIOR TO SUBMITTING PFH FORM

1. Review the HRPP SOP noted above under resources prior to submission of the Personal Financial Holdings (PFH) form to the Institute DEC office of the protocol Principal Investigator (PI)
2. Determine if the protocol is “covered” under this SOP. If you are not sure, discuss with the PI.
3. Confirm with the PI if there are any patents (both NIH and other) related to the study that are held by either the NIH, the PI or any of the Key Study Personnel (KSP).
4. Determine who the “covered” KSP are who are participating in the protocol.
5. Send the Conflict of Interest (COI) guide to all individuals serving as KSP on the protocol via the study correspondence in iRIS.
6. Send the COI Certification document supplement F to NIH employees, SGEs, and IPAs serving as Key Research Personnel and not listed as investigators who are serving in covered roles. This form is also used for staff with a “Fellow” status in NED.
7. Send the COI Certification document supplement G to non-NIH employees serving in covered roles. Note that on this form all individuals MUST sign the top signature line. The second line is only if they are the employee of an institution which has its own COI policy.
8. Non-NIH federal employees do not need to sign any form.
9. If you are submitting the PFH for a non-NCI PI, you will need to submit the form using the procedure and system of the Institute that the PI belongs to.
STEP 2: PFH SUBMISSION FOR INITIAL REVIEW

1. Complete the study application in iRIS. See the CCR SOP: NCI IRB submission and response: New protocol.
   - iRIS log in: https://iris.nci.nih.gov/iMedris/
2. Complete the “DEC Clearance Submission Form” in iRIS. This is the iRIS name for the Personal Financial Holdings Form.
3. Attach the title page of the protocol and the certification forms, if applicable.
4. Submit the form for DEC review. The DEC form does not require PI signature for submission.
5. You will receive the DEC Clearance back via iRIS from the NCI DEC. Attach this document to your IRB submission in iRIS.
6. Update the study application with the dates submitted to and cleared by the DEC office.
   *Note: All expedited actions must have the clearance included in the packet at the time of submission to the IRB.
   If you are submitting an action for full board, you can submit the form to the IRB without the DEC clearance attached. The date cleared date does not need to be filled in to submit the form. When you receive the DEC Clearance, submit it via email to NCI IRB Admin.

STEP 3: PFH SUBMISSION FOR AMENDMENTS

1. Any amendment involving the addition of any covered personnel to a covered protocol, any changes related to the use of commercial products, or any change to an IND/IDE requires the submission of the PFH to the DEC for review.
2. If adding non NIH personnel, obtain COI certification. Distribute COI guide to any new covered KSP via Study Correspondence in iRIS.
3. Complete a new DEC form in iRIS to indicate the relevant changes.
4. Attach the title page of the protocol and the certification forms, if applicable.
5. If you are only removing a KSP, a DEC review is not required. If you are submitting a PFH to the DEC for a combined Continuing Review (CR) and amendment, and removing a KSP, you will need to:
   - Create a new DEC clearance form in iRIS.
   - Click on “add investigator” to navigate to the screen where you indicate the individuals you are adding/removing
   - Include the individuals you are removing and note that it is a deletion of investigator
6. Submit the form for DEC review. The DEC form does not require PI signature for submission.
7. You will receive the DEC Clearance back via iRIS from the NCI DEC. Attach this document to your IRB submission in iRIS.
   *Note: All expedited actions must have the clearance included in the packet at the time of submission to the IRB.
If you are submitting an action for full board, you can submit the form to the IRB without the DEC clearance attached. When you receive the DEC Clearance, submit it via email to NCI IRB Admin.

STEP 4: PFH SUBMISSION FOR CONTINUING REVIEW

1. Submit the DEC Clearance request at the time of first notification, as clearance could delay CR approval.
2. Check that current Protocol Title Page matches:
   a. The list of Key Study Personnel in iRIS
   b. The Clinical Center protocol query system: http://pqrs.cc.nih.gov/
3. Complete DEC Clearance submission form in iRIS (NCI PIs only)
4. Include copy of title page of the protocol
5. Submit the form for DEC review. The DEC form does not require PI signature for submission.
6. You will receive the DEC Clearance back via iRIS from the NCI DEC. Attach this document to your IRB submission in iRIS.

Note: All expedited actions must have the clearance included in the packet at the time of submission to the IRB.

If you are submitting an action for full board, you can submit the form to the IRB without the DEC clearance attached. When you receive the DEC Clearance, submit it via email to NCI IRB Admin.